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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,954	02/15/2002	Akira Kaji	K0448/7012	3440
23628 7590 07/10/2008 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	
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			07/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,954	KAJI ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 52-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 1 and 52-59 are pending in the application.
- [2]** Receipt of a Pre-Appeal Brief Request for Review, filed on 12/6/07, is acknowledged.
- [3]** Applicant's arguments in the Pre-Appeal Brief Request, filed on 12/6/07, have been fully considered. Based on the decision rendered in the Pre-Appeal Conference, the finality of the rejection of the last Office action is withdrawn. All of the objection(s) and rejection(s) as set forth in the Office action mailed on 6/4/07 have been maintained and a new rejection under 35 U.S.C. 101 has been added as set forth below.
- [4]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim for Domestic and Foreign Priority

- [5]** Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. PCT/JP00/03639, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claim 1 (claims 52-59 dependent therefrom) has been amended to recite, “employing a three-dimensional structure of the conserved active site of RRF protein, which protein binds ribosomal RNA and recycles ribosomes...wherein the conserved active site comprises Arginine at positions 110, 129, and 132 according to Table 8.” At p. 5, top of the instant remarks, applicant points to pp. 11, 17, 21, 48, and original claim 1 as showing support for the added limitations. After reviewing applicant’s cited disclosure, the examiner can find descriptive support for active site residues Arg110, Arg129, and Arg132 of SEQ ID NO:1 (see, e.g., p. 11, lines 15-17). However, the examiner can find no descriptive support for Arg110, Arg129, and Arg132 of SEQ ID NO:1 (or Table 8 structural coordinates) being *conserved* throughout members of the RRF protein family and/or the use of a 3-D structure of the “*conserved* active site of RRF” comprising Arg at positions 110, 129, and 132. Applicant is invited to show support the noted limitation(s). In the absence of adequate descriptive support for the noted limitation, the claims have been accorded the effective filing date of the instant application, *i.e.*, 2/15/02.

Specification/Informalities

[6] The objection to the specification as being inconsistent in referring to Table 8 as being the structure coordinates of the RRF of SEQ ID NO:1 (see instant specification amendment) is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 6 beginning at p. 2. Applicant does not appear to traverse this objection in the Pre-Appeal Brief Request filed on 12/6/07.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[7] Claims 1 and 52-59 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to methods for identifying a compound capable of binding to an active site of RRF, encompassing methods of computerized, *i.e.*, *in silico*, screening. The claims are viewed as an "abstract idea", *i.e.*, a "judicial exception", since the methods involve manipulation of structural coordinate data using a computer algorithm. According to MPEP 2106.IV, "A claimed invention is directed to a practical application of a 35 U.S.C. 101 judicial exception when it: (A) 'transforms' an article or physical object to a different state or thing; or (B) otherwise produces a useful, concrete and tangible result". The claimed methods do not "transform" the data to a "different state or thing" and thus, to qualify as patent eligible subject matter, the claimed invention, as a whole, must accomplish a practical application. That is, it must produce

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a “useful, concrete and tangible result.” *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998).

Note that the “useful result” aspect of the practical application test requires significant functionality to be present. See *Arrhythmia Research Tech. v. Corazonix Corp.*, 958 F.2d 1053, 1057, 22 USPQ2d 1033, 1036 (Fed. Cir. 1992). In this case, the claimed methods do not produce a “useful, concrete and tangible result.”

Applicant may argue the methods of the claims, being methods to “design” or “select” compounds would provide a result set of a number of lead compounds with an increased probability of binding to the protein whose structure was input. However, it is noted that there is no *active method step* that *selects for* compounds that bind to an RRF active site represented by the 3-D model or structural coordinates that would provide a result set of a number of lead compounds with an increased probability of binding to the protein whose structure was input. As such, the claimed methods are not deemed to have a “practical application” and thus the claimed invention is considered to be non-statutory subject matter.

Applicant may further argue that the method of claims 54-59 requires that the compound be synthesized (claim 54) and optionally contacted with the binding site in the presence of a substrate (claim 57). However, these steps can broadly, but reasonably be interpreted as steps practiced *in silico*. Regarding claim 54, there is no claim limitation to require that the computerized model of a “compound” be, *e.g.*, transformed into a physical molecule or transformed such that it is displayed on a visual output device. Regarding claim 57, the step of “contacting” can broadly, but reasonably

be interpreted as a step practiced *in silico* and without transformation of the structural coordinate data of the compound, particularly as there is no claim limitation to require the step be practiced *ex silico*, e.g., contacting *in vitro*. In the absence of such limitations, the claims have been broadly, but reasonably interpreted as encompassing active steps that are practiced *in silico* without requiring transformation of the structural coordinate data.

Claim Rejections - 35 USC § 112, Second Paragraph

[8] The rejection of claims 1 and 52-59 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “the conserved active site of RRF protein” is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 7 at p. 3. Applicant does not appear to traverse this rejection in the Pre-Appeal Brief Request filed on 12/6/07. In this case, while a skilled artisan would recognize whether an RRF has Arg at positions 110, 129, and 132, the conserved active site is not limited to these positions in view of the recitation of “comprises Arginine at positions...” and it is unclear from the claims and the instant specification as to the amino acids of an RRF or region(s) of RRF, other than Arg at positions 110, 129, and 132, that are considered to be included within a “conserved” active site of RRF from those that are not. It is suggested that applicant clarify the meaning of the noted phrase.

[9] Claim 1 (claims 52-59 dependent therefrom) is indefinite in the recitation of “Arginine at positions 110, 129, and 132 according to Table 8” because it is unclear as

to whether this phrase is to be interpreted as meaning the recited residues have the structural coordinates of Table 8, or whether Table 8 is to be treated as providing the amino acid sequence of the RRF and the phrase is to be interpreted as meaning Table 8 provides a reference sequence for positions 110, 129, and 132. It is suggested that applicant clarify the meaning of the noted phrase.

Claim Rejections - 35 USC § 112, First Paragraph

[10] The new matter rejection of claims 1 and 52-59 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 8 beginning at p. 3. Applicant does not appear to traverse this rejection in the Pre-Appeal Brief Request filed on 12/6/07.

[11] The written description rejection of claims 1 and 52-59 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 9 beginning at p. 4.

RESPONSE TO ARGUMENT: At p. 3, item 4 of the Pre-Appeal Request filed on 12/6/07, applicant appears to address the instant rejection by arguing the broadest reasonable interpretation of the claims does not include homology models, referring to remarks filed on 3/26/07 at pp. 5-6.

Applicant's argument has been fully addressed in the Office action mailed on 6/4/07. See particularly paragraph 9 beginning at p. 4. At least for the reasons set forth therein, applicant's argument is not found persuasive.

[12] The scope of enablement rejection of claims 1 and 52-59 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 10 beginning at p. 8.

RESPONSE TO ARGUMENT: At pp. 2-3, items 3-4 of the Pre-Appeal Request filed on 12/6/07, Applicant appears to address the instant rejection by arguing: 1) the claims require the 3-D structure contain the conserved active site residues of Arg110, Arg129, and Arg132 of a functional RRF polypeptide and 2) the broadest reasonable interpretation of the claims does not include homology models, referring to remarks filed on 11/23/05 at pp. 7-10; remarks filed on 6/8/06 at p. 6; and remarks filed on 3/26/07 at pp. 5-7.

Applicant's argument has been fully addressed in the Office action mailed on 6/4/07. See particularly paragraph 10 beginning at p. 8. At least for the reasons set forth therein, applicant's argument is not found persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[13] Claims 1 and 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaji et al. (WO 00/75182 A1; "Kaji"). The instant rejection is based on an effective filing date of 2/15/02 for the claimed invention for reasons as noted above. Since the instant application is a 371 national stage filing of PCT/JP00/03639, which published as WO 00/75182, the instant specification has been relied upon as being an English-language translation of the reference of Kaji. The claims are drawn to methods for identifying a compound capable of binding to a conserved active site of RRF comprising Arg at positions 110, 129, and 132 according to Table 8.

CLAIM INTERPRETATION: As noted above, neither the claims nor the specification specifies the region(s) or amino acid(s) other than Arg at residues 110, 129, and 132 that are intended as being "the conserved active site" of RRF. In the interest of advancing prosecution and in applying the broadest reasonable interpretation of the claims, the "conserved active site" of RRF has been interpreted as encompassing only Arg at positions 110, 129, and 132 as "the conserved active site" of RRF.

Kaji discloses 3-D structural coordinates of *Thermotoga maritima* RRF at Table 8 (pp. 64-129) and teaches the use of the 3-D structural coordinates to generate a 3-D structure of RRF and design an inhibitory or binding compound using rational drug design that binds to the RRF active site (pp. 21-23). Kaji teaches the active site residues of RRF of SEQ ID NO:1 are Arg at positions 110, 129, and 132 (p. 11, middle and p. 17, bottom). Kaji further teaches the compound can be screened "by use of a computer on a chemical entity or compound that can bind to RRF" (p. 23, top) or the compound may be designed "wholly or anew" by using the active site of RRF (p. 29,

top) and the compound can be prepared and tested for its inhibitory activity toward RRF (p. 26, top). This anticipates claims 1 and 52-59 as written.

Claim Rejections - 35 USC § 103

[14] The rejection of claim(s) 1 and 52-59 under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Patent 5,856,116; cited in the IDS filed 2/18/2005; cited in a prior Office action) in view of Kaji et al. (*Biochem Biophys Res Comm* 250:1-4, 1998; cited in a prior Office action) and In re Gulack 217 USPQ 401 (Fed. Cir. 1983) is maintained for the reasons of record as set forth in the Office action mailed on 6/4/07. See particularly paragraph 11 beginning at p. 12.

RESPONSE TO ARGUMENT: At p. 2, items 1-2 of the Pre-Appeal Request filed on 12/6/07, Applicant appears to address the instant rejection by arguing: 1) protein coordinates are not merely descriptive matter and 2) *In re Gulack* is inapplicable to the claimed invention, referring to remarks filed on 11/23/05 at pp. 11-14; remarks filed on 6/8/06 at pp. 7-8; and remarks filed on 3/26/07 at pp. 7-9.

Applicant's argument has been fully addressed in the Office action mailed on 6/4/07. See particularly paragraph 11 beginning at p. 12. At least for the reasons set forth therein, applicant's argument is not found persuasive.

Conclusion

[15] Status of the claims:

Claims 1 and 52-59 are pending.

Claims 1 and 52-59 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656